

III. Sample Rules for implementing NELAC ADMINISTRATIVE RULES CHAPTER __, DIVISION

Purpose

These rules are for the purpose of implementing Chapter ____ 1999 ____ Laws and the ____ Drinking Water Quality Act of 1981. Chapter ____ states that the ____ Health Division, hereafter referred to as the Division, shall by adopting standards in concurrence with the Accrediting Authority, implement an environmental laboratory accreditation program hereafter referred to as the ----- Environmental Laboratory Accreditation Program (ELAP). These rules establish requirements for the accreditation of laboratories analyzing environmental samples under the guidance of the Clean Air Act (CAA), Clean Water Act (CWA), Safe Drinking Water Act (SDWA), and the Resource, Conservation and Recovery Act (RCRA). The Division shall accept ELAP accreditation for ____ that states that water samples from public water systems shall be analyzed in a laboratory approved by the Division.

Stat. Auth: _____ and __, Chapter __, 1999 __ Laws

Scope

- (1) These rules apply to environmental laboratories seeking accreditation and performing environmental testing.
- (2) Accreditation as described in these rules is required for all environmental laboratories reporting drinking water analysis results to the Division.

Adoption by Reference

All standards, listings and publications referred to in these rules are, by those references, made a part of these rules as though fully set forth. Copies are available through the Division, ____ State Public Health Laboratory.

Stat. Auth: _____ Chapter _____ Laws

Severability

These rules are severable. If any rule or part thereof or the application of such rule to any person or circumstance is declared invalid, that invalidity shall not affect the validity of any remaining portion of these rules.

Stat. Auth: ____ Chapter _____ Laws

Definitions

As used in these rules, unless the context indicates otherwise:

- (1) Accrediting Authority means the official accrediting authority for the ____ Environmental Laboratory Accreditation Program comprised of the Assistant Director for Health or designee, the Laboratory Administrator of the Department of Environmental Quality or designee and the Laboratory

Administrator of the Department of Agriculture or designee.

(2) Clean Air Act (CAA) means the enabling legislation, 42 U.S.C. 7401 et seq. (1974), Public Law 91-604, 84 Stat. 1676 Public Law 95-95, 91 Stat., 685 and Public Law 95-190, 91 Stat., 1399, that empowers the EPA to promulgate air quality standards, monitor and enforce them.

(3) Clean Water Act (CWA) means the enabling legislation under 33 U.S.C. 1251 et seq., Public Law 92-50086, Stat. 816 that empowers the EPA to set discharge limitations, write discharge permits, monitor and bring enforcement action for non-compliance.

(4) Environmental laboratory means a fixed location or mobile facility that analyzes environmental samples in a controlled and scientific manner.

(5) National Environmental Laboratory Accreditation Conference (NELAC) means the voluntary organization of state and federal environmental officials and interest groups purposed primarily to establish mutually acceptable standards for accrediting environmental laboratories.

(6) National Environmental Laboratory Accreditation Program (NELAP) means the program established and administered by the EPA to oversee the implementation of the NELAC Standards.

(7) NELAC Standards means the adopted **July 1999 NELAC Constitution, By-Laws, and Standards (EPA600/R-99/068)** document describing the elements of laboratory accreditation that was developed and established by the consensus principles of NELAC and meets with the approval requirements of NELAC procedures and policies.

(8) NELAP approved accrediting authority means a state or federal department/agency that has been approved by NELAP as being an entity whose accreditation and assessment program meets all of the requirements of the NELAC Standards.

(9) On-site assessment means an on-site visit to the environmental laboratory to verify items addressed in the ___ELAP application and to evaluate the facility and analytical performance for conformance with the NELAC Standards.

(10) ___ Health Division means Health Division of the ___ Department of Human Resources.

(11) ___ELAP approved assessor means an assessor whose qualification has been evaluated by ORELAP and found to meet NELAC Standards for laboratory on-site assessors.

(12) Primary Accreditation means accreditation by a NELAP approved accrediting authority based on a laboratory's compliance to NELAC Standards after a review of the laboratory's application, Quality Manual, PT results and on-site inspection results as described in the NELAC Standards.

(13) Proficiency testing (PT) means the analysis of samples obtained from providers that meet the NELAC standards for PT providers. The composition of the sample is unknown to the laboratory performing the analysis, and is used in part to evaluate the ability of the laboratory to produce precise and accurate results.

(14) Public water system means a water system as defined in _____ Quality Manual (QM) means a document stating the management policies, objectives, principles, organizational structure and authority, responsibilities, accountability, and implementation of a laboratory to ensure the quality of its product and the utility of its product to its users.

(16) Resource Conservation and Recovery Act (RCRA) means the enabling legislation 42 U.S.C. section 6901 et seq.(1976) that requires the EPA to protect human health and protecting and monitoring the environment by regulating hazardous waste disposal practices.

(17) Safe Drinking Water Act (SDWA) means the SDWA enacted in 1974 and the Safe Drinking Water Amendments of 1986, 42 U.S.C. 300f et seq., Public Law 93-523, that is the enabling legislation that requires the EPA to protect the quality of drinking water in the U.S. by setting maximum allowable contaminant levels, monitoring, and enforcing violations.

(18) These rules means the ____ Administrative Rules encompassed by ____ through ____.

(19) United States Environmental Protection Agency (EPA) means the federal government agency with the responsibility for protecting public health and safeguarding and improving the natural environment (i.e., air, water, and land) upon which human life, Chapter ____ Laws

Schedule for Requesting Accreditation, Period of Accreditation

(1) Laboratories in Oregon will be considered to be accredited by __ELAP after the laboratory has requested accreditation, been evaluated by __ELAP and has met all criteria in accordance with ____

(2) Beginning July 1, 2000, the accreditation period is for one year with subsequent accreditation periods beginning quarterly (October 1, January 1, April 1, July 1).

(3) Laboratories must reapply for __ELAP approval annually, with the application for the July 1 accreditation period commencement to be received by __ELAP on or before February 15 of the same year; May 15 of the same year for the October 1 accreditation period commencement; August 15 of the previous year for the January 1 accreditation period commencement and November 15 of the previous year for the April 1 accreditation period commencement. Stat. Auth: __, Chapter __, 1999 ____ Laws

Approval Requirements

(1) This rule and the NELAC Standards describe the procedure for obtaining and maintaining accreditation.

(2) __ELAP accreditation can be granted, denied, suspended, or revoked in total or in part as described in the NELAC Standards.

(3) In no case shall a laboratory be accredited that does not comply with the NELAC Standards as specified in this rule.

(4) The elements for accreditation shall include but are not restricted to:

(a) Application for accreditation

(A) __ELAP will make applications available to all laboratories requesting an application.

(B) The laboratory must request __ELAP accreditation by completing and submitting to __ELAP an acceptable application that includes all elements as required by the NELAC Standards.

(b) Laboratory's participation in a biennial on-site assessment (s) as required by the NELAC Standards

(c) Laboratory's participation in Proficiency Testing (PT) and the obtaining of acceptable PT results according to the NELAC Standards

(d) A Quality Manual (QM) that includes all elements as set forth in the NELAC Standards

(e) Laboratory staff members that meet the NELAC Standards for training and experience for their responsibilities within the environmental laboratory

(f) Creation and retention of all records pertaining to samples and analyses, including chain of

custody documents, log books, work sheets, raw data, calculations, quality assurance data, and reports according to NELAC Standards

(g) Laboratory's full payment of all appropriate fees as described in section _____ Laws

Action Response for Laboratory Drinking Water Analysis Results

(1) The laboratory must notify the water system and, if authorized by the public water system, the Division of all valid sample results that exceed the maximum contaminant levels in _____ within one working day.

(2) The laboratory must notify the public water system and, if authorized by the water system, the Division of all unregulated contaminants detected and their concentrations from each specific method used to measure the regulated contaminants.

(3) The laboratory must use report forms that have been approved by the Division for reporting drinking water test results to the Division.

Stat. Auth: _____

Procedure for Contesting Actions of __ELAP

The procedure for contesting the actions of __ELAP regarding denial, suspension and revocation of accreditation, or other changes in accreditation status is in accordance with the Administrative Procedures Act, _____

Stat. Auth.: _____, Chapter _____ 1999 _____ Laws

Accreditation of Out-of-State Laboratories

(1) __ELAP shall accredit out-of-state laboratories that are eligible for reciprocal accreditation provided:

(a) The laboratory is accredited by a state recognized as a NELAP accrediting authority for those fields of testing in which the laboratory is requesting accreditation pursuant to this rule.

(b) The laboratory submits to __ELAP an acceptable application as described in section _____ of this rule.

(c) The laboratory pays all appropriate fees as described in section _____ of this rule.

(2) __ELAP may accredit out-of-state laboratories which are located in states which do not have NELAP approved accrediting authority for the Fields of Testing and/or Programs in which the laboratory desires accreditation provided that the laboratory complies with all the requirements in section _____ of these rules.

Stat. Auth: __, Chapter _____, 1999 _____ Laws

Display of Certificate

Accredited environmental laboratories shall post or display their most recent __ELAP accreditation certificate and their __ELAP-accredited fields of testing in a prominent place in the laboratory facility.

Stat. Auth: _____, Chapter _____ Laws

Fee Schedule

Fees will be charged to environmental laboratories according to the following schedule.

(1) Payment of a non-refundable application fee must accompany each application.

(a) For laboratories located in ____, one of three levels of fees, Tier 1 at \$450, Tier 2 at \$900 and Tier 3 at \$1,600 will be charged. The Tiers will be determined by the total number of points derived from the number of Fields of Testing requested for accreditation listed in section (2)(a) through (c) of this rule.

(A) Each Basic Field of Testing has a multiplier of 1.

(B) Each Moderate Field of Testing has a multiplier of 3.

(C) Each Complex Field of Testing has a multiplier of 5.

(D) The total number of points is determined by first summing the number of Fields of Testing within each category (Basic, Moderate or Complex) and then multiplying the sums by their appropriate multiplier as given in this rule. The sum of these results determines the total number of points for each laboratory. Laboratories with a total of 1-10 points are to be considered Tier 1 laboratories, 11 to 25 points are Tier 2 laboratories and 26 or more points are Tier 3 laboratories.

(b) For each out-of-state laboratory requesting ____ approval, one of three levels of fees, Tier 1 at \$1,050, Tier 2 at \$1,500 and Tier 3 at \$2,200 will be charged with each Tier determined according to section (1) (a) of this rule.

(c) If a laboratory fails to submit an acceptable application after two attempts, the application will be rejected and the laboratory may reapply and must pay a new non-refundable application fee as determined in this rule.

(d) If a new owner acquires the laboratory and wishes the laboratory to remain accredited, the laboratory must submit a new application, pay the application fee and be subject to a new on-site inspection and payment of assessment and on-site fees as described in this rule.

(2) Upon __ELAP's review of a laboratory's application, each laboratory requesting primary accreditation through __ELAP will be charged an assessment fee based on the number Fields of Testing and Programs as follows:

(a) \$90 will be charged for each of the following Basic Fields of Testing requested for accreditation:

(A) gravimetric

(B) microbiology

(C) microscopy

(D) physical

(E) probe

(b) \$300 will be charged for each of the following Moderate Fields of Testing requested for accreditation:

(A) atomic absorption - flame

(B) atomic absorption - furnace

(C) automated colorimetric

(D) gas chromatography - volatiles

(E) gas chromatography - extractables

(F) high pressure liquid chromatography

(G) immunoassay

(H) instrumental

- (I) ion chromatography
- (J) manual colorimetric
- (K) radiation
- (L) whole effluent toxicity

(c) \$450 will be charged for each of the following Complex Fields of Testing requested for accreditation:

- (A) gas chromatography/mass spectrometry - volatiles
- (B) gas chromatography/mass spectrometry - extractables
- (C) inductively coupled plasma
- (D) inductively coupled plasma/mass spectrometry
- (E) X-ray

(d) An additional cost of \$10 for Basic Fields of Testing, \$30 for Moderate Fields of Testing and \$45 for Complex Fields of Testing will be charged for each additional Program per Field of Testing for which the laboratory has requested approval. The Programs are:

- (A) CAA
- (B) CWA
- (C) SDWA
- (D) RCRA

(e) Assessment fees must be paid during the accreditation period in which the on-site inspection is to be performed but must be paid before the on-site inspection will be scheduled.

(3) All environmental laboratories requesting primary accreditation through __ELAP must pay an on-site inspection fee for each on-site inspection.

(a) All environmental laboratories located in ____ must pay \$350 per inspection prior to scheduling and performing each required on-site inspection and additional inspections as requested by the laboratory for approval for additional Fields of Testing and/or Programs.

(b) All environmental laboratories located in ____ must pay \$350 per inspection for each inspection performed due to just cause according to NELAC Standards.

(4) All out of-state environmental laboratories must pay all on-site inspection costs incurred by __ELAP approved assessors to perform the on-site inspection. If third party assessors are used, __ ELAP may require the lab to pay the on-site inspection costs directly to the assessor according to the schedule of the assessor for all required inspections.

(5) Accredited laboratories requesting additional accreditation during the accreditation period must pay the difference in costs, i.e., application fee, assessment fee and on-site fee, that may result from this increase in the laboratory's scope of accreditation.

Stat. Auth: Chapter , 1999 ____ Laws

Civil Penalties

(1) In addition to any other penalty provided by law, the Division, in collaboration with the Accrediting Authority, may impose a civil penalty not to exceed \$500 per day per violation upon any and all laboratories that willfully or negligently commit any of the following:

- (a) falsely purport to be __ELAP accredited;

- (b) improperly use their __ELAP accreditation status in order to mislead;
 - (c) use the NELAC\NELAP logo in catalogs, advertisements, business solicitations, proposals, quotations, laboratory reports and other materials without proper authorization.
- (2) The Division reserves the right to pursue other remedies and may take any other disciplinary action against alleged violators.
- (3) In establishing the amount of the penalty for each violation, the Division will consider, but not be limited to the following factors:
- (a) The gravity and magnitude of the violation;
 - (b) The laboratory s previous record of complying or failing to comply with this rule.
 - (c) The laboratory s history in taking all feasible steps or in following all procedures necessary or appropriate to correct the violation; and,
 - (d) Such other considerations as the Division may consider appropriate.
- (4) The Division in collaboration the Accrediting Authority may deny, suspend or revoke accreditation of any laboratory that fails to pay on demand a civil penalty that has become due and payable, provided that it first gives the laboratory an opportunity for a hearing as outlined in ____
- Stat. Auth.: Chapter ____, 1999 ____ Laws